

Technical Support Section Efficacy Review-II

Disinfectants Branch

EPA.Reg. No.or File Symbol 211-36

Data Division Received 02-21-86

Data Accession No(s). Not Accessioned

Product Manager No. PM 32

Product Name Tri-Cen

Company Name Central Chemical Company, Inc.

202.0 Recommendations

202.1 Data Supporting Health-Related Uses

The submitted data support this product as a one-step disinfectant-cleaner against human pathogens (Salmonella choleraesuis, Staphylococcus aureus, Pseudomonas aeruginosa) in hospital/general use areas when used at a 1:128 dilution, to thoroughly wet hard, non-porous surfaces with a moderate organic soil load (5% blood serum) for a 10-minute contact time.

202.2 Efficacy Claims Not Supported By Data

No data were submitted to support efficacy of the product at a 1:128 dilution in the presence of blood serum against the human pathogen, Trichophyton mentagrophytes, that is claimed on the proposed label submitted.

202.3 Non-Health-Related Uses

Submission of data are not required to support virucidal claims against the animal viruses specified on the proposed label.

202.4 Tuberculocidal Claims

Previously accepted data support this product as tuberculocide when a 1:100 dilution of the product is applied to thoroughly wet precleaned, hard surfaces for a 10-minute contact time.

202.5 Labeling Revisions

1. The label must indicate that 1 oz of product per gallon of water is 1 part of Tri Cen to 128 parts of water, not 256 parts of water.
2. The recommendation of this product as a shoe bath sanitizer will be acceptable only if qualified to indicate that the sanitizing action is against animal pathogens.
3. The virucidal claim on the label must be corrected to read: "Avian Infectious Bronchitis Virus," and the specific viruses claimed must be keyed to the asterisk on the front panel.

4. In lieu of supporting data, the fungicidal claim under efficacy performance must be deleted.
5. The adequate label directions for using this product at a 1:100 dilution on precleaned hard surfaces for a 10-minute contact time must be provided in order to recommend tuberculocidal and pathogenic fungicidal activity for this product.
6. The claim "hospital-grade" is not acceptable. Claims such as "hospital disinfectant" or "for hospital use" are acceptable.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 03-17-86

OUT 06-19-86

Reviewed By Dorothy M. Portner

Date 06-19-86

EPA Reg. No. 211-36

EPA Petition or EUP No. None

Date Division Received 02-21-86

Type Product Hospital/General Disinfectant

Data Accession No(s). Not Accessioned

Product Manager PM-32

Product Name Tri-Cen

Company Name Central Chemical Company, Inc.

Submission Purpose Resubmission to change use dilution and to
add additional use patterns

Type Formulation Liquid concentrate to be used diluted

Active Ingredient(s):

8

Sodium ortho-benzyl-para-chlorophenate.....	4.40
Sodium ortho-phenylphenate.....	2.82
Sodium para-tertiary-amylphenate.....	2.49
Sodium dodecylbenzenesulphonate.....	2.12

200.0 Introduction

200.1 Use

Proposed label is attached.

200.2 Background Information

The submission, received 2-21-86, is an amended application to change the use dilution from 1:100 to 1:128 on all claims except the tuberculocidal claim, and to add use directions as a one-step disinfectant-cleaner for poultry and swine premise surfaces. A proposed label and efficacy data were provided.

201.0 Data Summary (Unaccessioned data)

The submitted bactericidal data were developed by Hill Top Research, Inc., Miami, Ohio except for the designated AOAC Use Dilution studies developed by Hazleton Biotechnologies Corporation, Vienna, Virginia.

201.1 Brief Description of Test

Method: AOAC Use Dilution Test
Exposure Period: 10 minutes at 20°C
Dilution Tested: 1:128
Organic Soil: 5% Serum
Subculture Medium: Letheen Broth
Incubation Conditions: 48 hours at 37°C

201.2 Test Results

Test Organism	Phenol Resist.	Survival After Dry	No. Positive/Total		
			058508*	088527	088514
S. choleraesuis	1:90	3.2×10^5	1/60	1/60	1/60
S. aureus	1:60	9.2×10^5	1/60	-	-
	1:65	4.5×10^6	-	0/60**	0/60**
P. aeruginosa	1:80	1.3×10^7	0/60	0/60	1/60

* 60-day storage stability sample.

** Data developed by Hazleton.

- Not tested.

201.3 Conclusions

1. The submitted data demonstrate a satisfactory performance of the product as one-step disinfectant-cleaner in medical and non-medical areas against S. choleraesuis, S. aureus, and P. aeruginosa in the presence of organic soil at a 10-minute contact time.
2. No data were submitted to support efficacy of a 1:128 dilution of the product in the presence of 5% blood serum against T. mentagrophytes claimed on the proposed label.
3. No data are required to support efficacy of a 1:128 dilution of the product in the presence of 5% blood serum against the additional animal viruses claimed on the proposed label.
4. Previously accepted tuberculocidal data were developed at a 1:100 dilution in the absence of organic soil; thus additional label directions will be required to clarify this use pattern.